

REMARKS

With entry of this amendment, claims 25, 30, and 45-48 are pending in the application. By this amendment, claims 30, and 45-48 have been amended for clarity, without prejudice. Claims 1-24, 26-29, 31-44 and 49-56 were previously canceled without prejudice, and Applicants continue to reserve the right to pursue the subject matter of these canceled claims in one or more related applications. All of the amendments herein are fully supported by the disclosure, and no new matter has been added to the application.

Patentability Under 35 USC § 112

Claims 30 and 45-48 are rejected under 35 USC § 112, first paragraph for alleged failure to comply with the written description requirement (Office Action at pp. 2-3).

Claims 30 and 45-48 are rejected under 35 USC § 112, first paragraph for alleged lack of enablement (Office Action at pp. 3-4).

Applicants respectfully traverse the foregoing grounds of rejection set forth at pp. 2-4 of the Office Action, and submit that the disclosure fully describes and enables the subject matter of original claims 30, and 45-48. In particular, Applicants submit that the specification provides descriptive and enabling support for methods to treat and prevent conditions involving mechanisms other than inhibition of dopamine uptake.

Nonetheless, the foregoing grounds of rejection are believed to be obviated by amendment of claims 30, and 45-48 herein, to clarify that the subject addictive disorders are “alleviated by inhibiting dopamine reuptake”. These amendments are presented for clarity in accordance with the Examiner’s suggestions, to advance certain aspects of the invention to issuance. Notably, the Examiner expressly concludes that the specification provides descriptive and enabling support for this subject matter (see Office Action at page 2, second full paragraph, and page 3, third full paragraph). Accordingly, without acceding to the merits of the foregoing rejection, the subject matter of the amended claims has been fully considered by the Office and deemed to satisfy the requirements of 35 USC § 112, whereby the rejection is rendered moot. Any subject matter withdrawn from prosecution by these amendments is withdrawn without prejudice, and Applicants reserve the right to pursue all additional subject matter supported by the disclosure in one or more related applications.

Patentability Under 35 USC § 103

Claims 25, 30, and 45-48 are rejected under 35 USC § 103(a) as allegedly unpatentable over Beer et al., US 6,204,284 B1. In particular, the Office relies upon Beer et al. for

allegedly disclosing use of a racemic mixture containing the active enantiomer of the instant claims to treat addictive disorder. The Office notes that the current invention is distinguished by virtue of using the “(-) isomer substantially free of the corresponding enantiomer instead of racemic mixture by Beer et al.” However, the Office asserts that that Beer et al. “have both isomers except in degrees”, on which basis the instant claims are allegedly *prima facie* obvious. In further comments, the Office submits that skilled artisans “would have known to use the (-) isomer at the time the invention was made” . . . based on the alleged motivation that it is “a well-established principal that an isomer is sometimes more reactive than the corresponding isomer or racemate.” (citing *In re Adamson*, 125 USPQ 233 (1960)).

Applicants respectfully traverse the foregoing grounds of rejection and submit that the subject matter of claims 25, 30, and 45-48 is neither disclosed nor suggested by Beer et al., US 6,204,284 B1.

Applicants submit that the Office has not established *prima facie* evidence of obviousness relating to the instantly claimed subject matter. Alternatively, if such case is deemed established, that the teachings of the instant disclosure evince unexpected results sufficient to overcome such *prima facie* evidence as proffered by the Office.

In the instant case, Applicants have resolved a novel (-) isomer, (-)-1-(3,4-DICHLOROPHENYL)-3-AZABICYCLO[3.1.0]HEXANE, which is neither resolved, nor characterized for any of its functional properties, by Beer et al. By the Office’s own evidence, it is unpredictable from a racemic mixture, or its established properties, that a successfully resolved (+) or (-) isomer will have activity comparable to that of the racemic mixture. While the Office cites a 1960 CCPA decision for the prospect that “an isomer is sometimes more reactive than the corresponding isomer or the racemate”, this evidence falls far short of comprehending the actual range of variability and unpredictability exhibited by enantiomeric compounds. It is equally true that in many instances of racemic mixtures, all or most of the activity resides in one enantiomer, while the other is largely or completely inactive.

In this context, Applicants respectfully submit that the general disclosure of a racemic mixture, projected to have a certain activity, fails to establish *prima facie* evidence that each of the respective enantiomers, when and if resolved, will exhibit the specified activity substantially as demonstrated or projected for the racemic mixture. Such disclosure as provided by Beer et al. in the instant case provides little in the way of specific, “practical” teachings regarding the usefulness of Applicants’ (-) isomer in the instantly claimed methods. From such evidence, it cannot be reasonably said that there was “a reasonable expectation of success” for practicing the instant invention--which notably involves the use of a previously

unresolved and uncharacterized isomer within a complex, unpredictable physiological pathway to yield effective inhibition of addictive disorders and other disorders potentially alleviated by inhibition of dopamine reuptake.

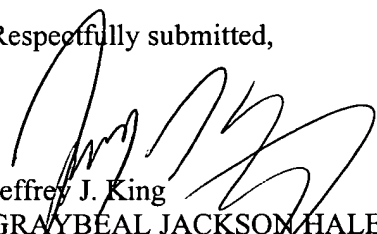
In view of the foregoing, Applicants respectfully submit that the Office has not established *prima facie* evidence that the instant claims are unpatentable over Beer et al., or, alternatively, that teachings of the instant disclosure, evincing usefulness of the (-) isomer within the subject methods, fail to establish "unexpected results" sufficient to overcome such *prima facie* evidence if found.

CONCLUSION

In view of the foregoing, Applicants believe that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at (425) 455-5575.

Respectfully submitted,



Jeffrey J. King
GRAYBEAL JACKSON HALEY, LLP
155 – 108TH Avenue N.E. – Suite 350
Bellevue, Washington 98004-5973
Telephone: (425) 455-5575
Facsimile: (425) 455-1046